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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/696,969	10/30/2003	Jason A. Demers	1062/D70	8503

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EXAMINER	
CORDERO GARCIA, MARCELA M	
ART UNIT	**PAPER NUMBER**
1654	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/696,969	DEMERS ET AL.	
	Examiner	Art Unit	
	MARCELA M. CORDERO GARCIA	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 June 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *26-71* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *26-71* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *09/06, 05/07, 11/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to the reply received on 9 June 2006.

Claims 26-71 are pending in the application. Claims 26, 33, 49, 52 and 56 have been amended. New claims 66-71 have been added.

Any rejection from the previous office action, which is not restated here, is withdrawn.

Claims 26-71 are presented for examination on the merits.

Rejections maintained

Specification

The use of the trademarks PEN110 and INACTINE (p. 8, l. 15) has been noted in this application. They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner that might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 26-71 are rejected under 35 U.S.C., second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention.

Claim 26 recites that the liquid controller is to be “operatively coupled” with the receiving chamber. It is unclear what this means. Is said coupling to take place as part of a mechanical operation (e.g., movement on the part of either controller or the receiving chamber) or are they to be coupled or linked together in terms of how they operate (e.g., functionally)? Applicant has not made this clear. Further, it is unclear what the “receiving chamber” comprises in that the specification does not discuss this structure in reference to the drawings. Also, there is no antecedent basis or description of the following elements in the specification disclosure: “container assembly controller” (claim 26, line 7; “liquid controller” (claim 26, line 10); "cover lock” (claim 32) and “pneumatically controlled member” (claim 33).

Claim 36 recites the limitation “wherein the receiving chamber at least partially extends outwardly from the housing”. There is insufficient antecedent basis for this limitation in the claim 26 from which it depends. It appears that the claim should depend rather on claim 35.

Claim 59 recites the limitation "wherein the receiving means at least partially extends outwardly from the housing". There is insufficient antecedent basis “or this limitation in claim 49. It appears that the claim should depend rather on claim 58.

The rest of the claims are rejected as being dependent upon a rejected base claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 26-29, 34-42, 49-52 and 57-66 and 69 are rejected under 35 USC 102(b) as being anticipated by Bloom et al. (US 6,070,761), cited by Applicants.

Claim 26 is drawn to an apparatus for mixing a substance with a liquid, the substance being contained in a container assembly having a sealed container that contains the substance, the container assembly also having a port assembly to permit substance to flow from the sealed container when coupled, the apparatus comprising: a receiving chamber for receiving the container assembly; A container assembly controller in communication with the receiving chamber for controlling coupling of the container and the port assembly without allowing decoupling of the container and the port assembly; and a liquid controller operatively coupled with the receiving chamber for controlling the flow of the liquid into the container to produce a combined substance and liquid. Claim 27 specifies that the liquid controller controls both the flow of liquid into the container and flow of the mixture out of the chamber (d), while claim 28 specifies that the container assembly controller mechanically moves at least a portion of the container assembly to couple the container with the port assembly (e). Claim 29

specifies that the container assembly controller includes logic for detecting the relative location of the container and port assembly (f). Claims 34-43 further specify that the liquid controller include logic that stores a value representing a predetermined amount of liquid to be received by the container assembly; that the apparatus further comprise a housing containing at least one of the container assembly controller and the liquid controller; that the receiving chamber at least partially extend outward from the housing; that the apparatus further comprises a sensor within the receiving chamber for detecting the location of the container within the receiving chamber for detecting the location of the container within the receiving chamber, that the receiving chamber be configured to contain the container assembly in a single orientation; that the apparatus further comprise a set of valves controlled by the liquid container to control the flow of liquid into the container; that the apparatus further comprise a cassette used by the liquid controller to measure the volume of liquid to be directed to the container; that the substance is a caustic solution and that the substance is an anti-pathogen compound, respectively. Claim 49 is drawn to an apparatus for mixing a substance with a liquid, said apparatus comprising means for receiving a container assembly having a sealed container that contains the substance; coupling means for controlling coupling of the container assembly and a port assembly that permits the substance to flow from the sealed container when coupled; and a flow means for controlling the flow of the liquid into the container to produce a combined substance and liquid. Claim 50 further specifies that the flow means also control the flow of the combined substance and liquid from the

container; claim 51 further specifies that the coupling means include means for mechanically moving at least a portion of the container assembly to couple the container with the port assembly; and claim 52 further specifies that the coupling means include means for detecting the relative locations of the container and the port assembly. Claims 57-65 further specify that the flow means include means for storing a value representing a predetermined amount of liquid to be received by the container assembly; that the apparatus further comprise a housing containing at least one of the coupling means and the flow means; that the receiving means at least partially extend outwardly from the housing; that the apparatus fu comprise a means for detecting the location of the container within the receiving means; that the receiving means be configured to contain the container assembly in a single orientation; that the apparatus further comprise a set of valves controlled by the flow means to control flow of liquid into the container,; that the apparatus further comprise a means for measuring the volume of the liquid to be directed to the container, the measuring means being used by the flow means; and that the substance be either caustic or anti-pathogenic, respectively.

Bloom et al. teach an apparatus (Figure 13) for mixing a substance with a liquid comprising: a sealed container 85; port assembly 118; receiving chamber 202 with hinged cover 86 for receiving the container; controller 207 for controlling coupling of the container and the port assembly (col. 17, II. 8-26); and liquid controller 88 comprising a cassette 77 and valves 112 (col. 16, II.. 54-64). The liquid controller controls flow of liquid to and from the container (col. 15, II. 47-58

and col. 16, ll. 54-64). With regard to instant claims 37 and 60, Bloom et al. also teach a container sensing device at col. 19, ll. 53-54. The newly introduced limitation "without allowing decoupling of the container and the port assembly" is deemed to still read upon the Bloom patent, e.g., Figure 9, which teaches clamp 125 and Fig. 12, 216 and 218 (col. 17) which inhibit decoupling of the container and port assembly. Please note that the limitation is not drawn to a specific length of time for which the decoupling is not possible. See also claims. The limitations of claims 66 and 69 are also taught by Bloom et al. See, e.g., Figures, especially Figures 9-15.

Therefore the reference is deemed to anticipate the instant claims above, as drafted.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 26, 33, 49, 56, 68, 70, 71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bloom et al. as applied to claims 26-29, 34-42, 49-52 and 57-65 above in view of Ko (US 6,527,758).

Claim 33 is drawn to the apparatus of claim 26 as further including a pneumatically controlled member within the receiving chamber, the pneumatically controlled member being capable of contributing to the coupling of the container

assembly in response to commands from the container assembly. Claim 56 is drawn to the apparatus of claim 49 as further including a pneumatically controlled means within the receiving means, the pneumatically controlled means being capable of contributing to the coupling of the container assembly in response to commands from the coupling means. Claims 68, 70-71 are drawn to pneumatic control.

With regards to claims 33, 56, 68, 70-71. Bloom et al. do not teach a pneumatically controlled member for contributing to the coupling of the container assembly. In Bloom et al., the container holder 207 is manually lowered by the clinician so that the spike 118 pierces the seal of the container 85. Ko teaches means for moving the spouts of containers into coupling engagement with receptacles at a docking station wherein the moving means comprises either manually controlled driven cams (22, 23; figures 2-5) pneumatically controlled means 29 (figure 10; col. 5, II. 55-62). It therefore would have been obvious to one of ordinary skill in the art at the time the invention was made to use pneumatic means for contributing to the coupling of the container assembly of Bloom et al. in view of the teaching of Ko that pneumatic means can be used in place of manual means for moving containers into coupling engagement with receptacles at a docking station.

Response to arguments

Applicants' arguments have been carefully considered but not deemed persuasive for the reasons of record and for the reasons set forth above. Please

note that claims 30-32, 43-48 and 53-55 were rejected under 112 2nd paragraph previously.

New grounds of rejection

Claim Rejections - 35 USC § 112

Claims 26-71 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

New Matter

The claims (claims 26 and 49 and dependent claims thereof) have been amended to incorporate the limitation "without allowing decoupling of the container and the port assembly". The portions of the application supporting such amendment were not pointed out.

Lack of Ipsis Verbis Support

The specification is void of any support that would clearly support the instant amendment. The specification does not teach the newly recited limitation.

Lack of Inherent Support

"While there is no in haec verba requirement, newly added claim limitations must be supported in the specification through express, implicit, or inherent disclosure." See MPEP 2163. Page 15, lines 15-19 describes the spike housing 344 also features an undercut vial receptacle locking feature 348 that engages the spike receptacle engagement teeth 204 of the vial receptacle 206

after spiking to permanently attach the spike receptacle 310 to the vial receptacle 206 after spiking. However, this feature is drawn to the apparatus of Figure 3D and there appears to be no specific support for the broad invention as claimed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARCELA M. CORDERO GARCIA whose telephone number is (571)272-2939. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia J. Tsang can be reached on (571) 272-0562. The

fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cecilia Tsang/
Supervisory Patent Examiner, Art Unit 1654

/Marcela M Cordero Garcia/
Examiner, Art Unit 1654

MMCG 03/09